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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,381	06/10/2005	Guenther Eissner	021149-000001	4749

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EXAMINER	
BOWMAN, AMY HUDSON	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,381	EISSNER ET AL.	
	Examiner	Art Unit	
	AMY BOWMAN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5,7-19 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5,7-19 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/28/05, 12/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 12/12/08 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 5/23/08 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 5, 7-19, and 39 are pending in the instant application.

This application contains subject matter of claim 5 that is drawn to an invention nonelected without traverse in the reply filed on 12/7/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's arguments with respect to all claim rejections have been considered but are moot in view of the new ground(s) of rejection.

It is noted that the rejections of record are moot in view of the instant claim amendments. However, new grounds of rejection are set forth below based upon the instant amendments. Applicant's arguments that are pertinent to the instant rejections are addressed below.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 4/28/05 and 1/21/09 have been considered by the examiner.

Claim Objections

Claim 39 is objected to because of the following informalities: The word "polydeoxyribonucleotide" is spelled “polydeoxyribomucleotide”. Appropriate correction is required.

Furthermore, claim 39 recites that the polydeoxyribonucleotide comprises the formula. The polydeoxyribonucleotide would not actually comprise the formula, but would rather be produced in accordance with the formula.

Response to Amendment

The declaration under 37 CFR 1.132 filed 12/12/08 is insufficient to overcome the rejection of the claims based upon scope of enablement (35 USC 112, 1st paragraph) as set forth in the instant Office action because: the showing of the declaration is not commensurate in scope with the claimed subject matter.

The declaration demonstrates treatment of tumor cells with 5-fluorouracil in the presence or absence of defibrotide or oligotide. The declaration demonstrates that defibrotide or oligotide counteracts that apoptotic effect of 5-flourouracil.

However, as instantly amended, the claims are directed to administering any immunosuppressant that comprises a nucleoside and any protective

oligodeoxyribonucleotide that follows the formula of claim 3 with resultant protection of one or both of a patient's epithelial or endothelial cells from one or both of apoptosis or activation induced by the immunosuppressant. The specific example of the declaration does not enable the full scope of possible combinations of immunosuppressants and protective oligodeoxyribonucleotides with the instantly recited outcomes.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, 8-12, 17-19, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At the outset, it is noted that the claims do not recite a specific “protective oligodeoxyribonucleotide”, but rather refer to an extremely broad genus of possible oligodeoxyribonucleotides that would result from the instantly recited formula/characteristics.

The claims encompass a method of treating a patient comprising administering an immunosuppressant comprising a nucleoside and administering any protective oligodeoxyribonucleotide that would result from the instant formulae and achieving

protection of one or both of the patient's epithelial or endothelial cells from one or both of apoptosis or activation induced by the immunosuppressant.

Although the specification discloses that fludarabine activates and damages endothelial and epithelial cells, leading to damage in situations where fludarabine is utilized for treatment, and that these cells can be protected by treatment with defibrotide, the specification does not describe an adequate species of "protective oligodeoxyribonucleotides" produced by the instant formula/guidelines to demonstrate that applicant was in possession of the claimed genus of oligodeoxyribonucleotides within the instant method at the time the invention was made. The instant genus of protective oligodeoxyribonucleotides is very large, embracing a huge genus of oligodeoxyribonucleotides that would result from the instant formulae/guidelines.

Applicant has not described a structure that would allow the skilled artisan to envision which oligodeoxyribonucleotides within the instant genus are considered protective and would have the desired outcome of achieving protection of one or both of the patient's epithelial or endothelial cells from one or both of apoptosis or activation induced by the immunosuppressant, such that the skilled artisan would recognize that applicant was in possession of the claimed scope at the time the invention was filed.

Since the specification does not sufficiently describe a structure to define which "protective oligodeoxyribonucleotides" produced according to the instant formula would achieve the instant method when administered in a method with any immunosuppressant comprising a nucleoside, the skilled artisan would not be able to readily envision which oligodeoxyribonucleotides of the instant genus would actually be

protective within the instant method and therefore could not be able to appreciate that the applicant was in possession of this genus within the instant method.

Response to arguments that are pertinent to the instant rejection

Applicant sets forth that the instant claim amendments further define the protective oligodeoxyribonucleotide and thus render the rejection moot.
The instant amendments recite a formula of random sequence and physico-chemical and chemical characteristics for the oligodeoxyribonucleotide. The instant specification discloses the formulae and property parameters, but does not set forth any structural characteristic to differentiate which of such a broad genus would yield protection as required by the instant method by counteracting the apoptotic activity of any immunosuppressant comprising a nucleoside. The formulae/characteristics do not define a genus of molecules that would necessarily result in the instantly recited outcome, but rather produce a huge genus of possible oligodeoxyribonucleotides wherein the skilled artisan would not be able to differentiate which act via the instant method and which would not so that the skilled artisan could recognize that applicant was in possession of such a broad genus at the time of filing.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, 7-19, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of administering defibrotide or oligotide to a patient undergoing treatment with fludarabine or 5-fluorouracil and resultant inhibition of flurdarabine or 5-fluorouracil induced apoptosis, does not reasonably provide enablement for a method of administering any protective oligodeoxyribonucleotide with the instant characteristics and any immunosuppressant comprising a nucleoside to a patient with the resultant desired effects. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in a determination of lack of enablement include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The instant claims are directed to a method of treating a patient comprising administering any immunosuppressant comprising a nucleoside and administering any

protective oligodeoxyribonucleotide according to the instant formulas with the outcome of protecting one or both of the patient's epithelial or endothelial cells from one or both of apoptosis or activation induced by the administration of the immunosuppressant.

The instant specification teaches delivering defibrotide *in vitro* in cultured endothelial cells treated with fludarabine and resultant inhibition of flurdarabine induced apoptosis, wherein fludarabine induces ICAM-1 expression.

Although the exemplification of the instant specification is strictly *in vitro*, the art teaches *in vivo* treatment of a patient with daunorubicin and etoposide, as well as intravenous delivery of defibrotide, as evidenced by Bairey et al. (American Journal of Hematology, April 2002, 69, pages 281-284)(of record and cited on the PTO-892 mailed on 5/23/08).

Therefore, there is no reason to believe that delivery of 5-fluorouracil, the elected immunosuppressant, or fludarabine, the immunosuppressant of the instant specification that was tested *in vitro*, would not successfully treat venoocclusive disease in the method of Bairey et al.

The declaration filed 12/12/08 supports such by demonstrating treatment of tumor cells with 5-fluorouracil in the presence or absence of defibrotide or oligotide. The declaration demonstrates that defibrotide or oligotide counteracts that apoptotic effect of 5-flourouracil.

However, as instantly amended, the claims are directed to administering any immunosuppressant that comprises a nucleoside and any protective oligodeoxyribonucleotide that follows the formula of claim 3 and 39 with resultant

protection of one or both of a patient's epithelial or endothelial cells from one or both of apoptosis or activation induced by the immunosuppressant. The specific example of the declaration does not enable the full scope of possible combinations of immunosuppressants and protective oligodeoxyribonucleotides with the instantly recited outcomes.

The specification and the state of the art do not reasonably provide enablement for a method of administering any protective oligodeoxyribonucleotide within the genus produced by the instant formulas to a patient undergoing treatment with any immunosuppressant comprising a nucleoside with the instantly recited outcome of protection of one or both of the patient's endothelial or epithelial cells from one or both of apoptosis or activation induced by the administration of the immunosuppressant, wherein in one embodiment the activation is enhanced expression of ICAM-1.

There is no guidance in the specification as filed that teaches how to mediate the instant method in a patient with any immunosuppressant comprising a nucleoside, which encompasses any agent comprising a nucleoside that suppresses the immune system in any way, via administering any protective oligodeoxyribonucleotide within the instant genus, which encompasses any oligodeoxyribonucleotide that protects from anything as long as it meets the instant formula guidelines, with a resultant protection of one or both of endothelial or epithelial cells from one or both of apoptosis or activation induced by the administration of the immunosuppressant, wherein in one embodiment the activation is enhanced expression of ICAM-1.

Given the teachings of the specification as discussed above, one skilled in the art could not predict *a priori* whether introduction of any protective oligodeoxyribonucleotide of the instant broad formulae and any immunosuppressant comprising a nucleoside to a patient would result in each of the instantly recited outcomes. Therefore, to practice the claimed invention, one of skill in the art would have to *de novo* determine which immunosuppressants and which protective oligodeoxyribonucleotides would together act in a manner to achieve the instantly recited outcomes. Without further guidance, one of skill in the art would have to practice a substantial amount of trial and error experimentation, an amount considered undue and not routine, to practice the instantly claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, **at the time the application was filed**, would not have taught one skilled in the art how to make and/or use the **full scope** of the claimed invention without undue experimentation (see MPEP 2164.01(a)).

Response to arguments pertinent to instant rejection

Applicant argues that the declaration by Dr. Eissner clearly demonstrates that the oligodeoxyribonucleotide according to the invention indeed protects endothelial cells and epithelial cells from immunosuppressant-mediated apoptosis. However, the claims are not directed to any specific protective deoxyribonucleotide or immunosuppressant combination, but rather a broad genus of possible combinations that are not

commensurate in scope with the showing of the declaration. The declaration demonstrates enablement of the scope that had been set forth as enabled in the office action mailed on 5/23/08. Specifically, the instant formulae set forth a very broad genus of molecules that would not necessarily achieve the instantly desired outcomes within the instant method with any immunosuppressant comprising a nucleoside. It would require undue experimentation for one skilled in the art to determine which combinations of agents within the instant criteria would result in the instant outcomes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 5, 7-19, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bairey et al. (American Journal of Hematology, April 2002, 69, pages 281-284), in view of De Luca et al. (Int. J. Cancer, 1997, 73, pages 277-282), and Sayer et al. (J Cancer Res Clin Oncol, March 2002, 128, pages 148-152).

It is noted that the references are of record and cited on the PTO-892 mailed on 5/23/08.

The instant claims are directed to a method of treating a patient with an immunosuppressant comprising a nucleoside and a protective oligodeoxyribonucleotide of the instant criteria and achieving protection of one or both of the patient's epithelial or endothelial cells from one or both of apoptosis or activation induced by the administration of the immunosuppressant. The claims further specify that the oligodeoxyribonucleotide is defibrotide and specify dosing ranges.

It is noted that the instant rejection is directed to an enabled embodiment of the instant invention, a method of administering 5-fluorouracil and defibrotide to treat a patient.

Bairey et al. teach a method of treating a patient undergoing treatment with an immunosuppressant, more specifically etoposide, the method comprising administering

defibrotide (see page 282, column 1). Bairey et al. teach administering daunorubicin, another immunosuppressant, after the treatment with defibrotide (see page 282, column 2).

Bairey et al. teach that defibrotide was administered at a dose of 12 mg/kg which was increased gradually to 30 mg/kg (see page 282, column 1), which is within the range of the instantly recited dosages. Bairey et al. teach that administration of intravenous defibrotide for 19 days induced complete resolution of hepatic venoocclusive disease.

Bairey et al. teaches that defibrotide increases fibrinolysis and may possess antithrombotic, anti-ischemic, and anti-inflammatory properties without significant anticoagulant effects. Bairey et al. teaches that defibrotide can avidly bind to vascular endothelium and increase the levels of endogenous prostaglandins and stimulate expression of thrombomodulin and that for these reasons defibrotide was selected to treat a condition, VOD, which was previously fatal (se page 283, column 2).

Bairey et al. does not teach administering the specific immunosuppressant 5-fluorouracil.

De Luca et al. teach that 5-fluorouracil is a conventional chemotherapeutic drug (see abstract).

Sayer et al. teach a method of treating a patient undergoing treatment with an immunosuppressant, more specifically methylprednisolone, the method comprising administering defibrotide (see abstract).

Sayer et al. teach administration of the immunosuppressant and defibrotide after allogeneic stem cell transplantation (see abstract). Sayer et al. teach that defibrotide was administered at a dose of 10 mg/kg up to 30/mg/kg per day (see page 149, column 2), which is within the range of the instantly recited dosages. Sayer et al. teach that defibrotide enhances tPA and thrombomodulin in endothelial cell cultures.

It would have been obvious to practice the method of Bairey et al. of administering defibrotide, combined with treatment with 5-fluorouracil. It would have been obvious to treat the patient with the immunosuppressant during allogeneic stem cell transplantation because Sayer et al. teaches administration of an immunosuppressant and defibrotide after allogeneic stem cell transplantation to treat the same disorder and therefore it would have been obvious to optimize the method via administering the compounds during the allogeneic stem cell transplantation as well.

It would have been prima facie obvious to perform routine optimization of the method of Bairey et al. with different known chemotherapeutic drugs; as well as to vary the sequence and dosage of the administration of the agents, as noted in *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the particular sequence of administration of the compounds or the dosing requirements used was other than routine, that the products resulting from the

optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

One would have been motivated to administer the compounds in varying order with varying doses during allogeneic stem cell transplantation, as these are each design choice elements of the methods of Bairey et al. or Sayer et al. One would have been motivated to alter the timing of administration in order to routinely optimize the combined methods of Bairey et al. and Sayer et al.

One would have been motivated to practice the method of Bairey et al. wherein the chemotherapeutic drug is 5-fluorouracil because 5-fluorouracil is a known chemotherapeutic drug to achieve the same desired benefit of treating the leukemia of the patient of Bairey et al. Importantly, Bairey et al. teach a method of administering a different immunosuppressant and the same protective deoxyribonucleotide as instantly recited, defibrotide, wherein Bairey et al. teaches administration of chemotherapeutic agents. Although the chemotherapeutic agents utilized in the method of Bairey et al. are etoposide and daunorubicin, one of skill in the art would certainly be motivated to try other known chemotherapeutic agents as a design choice and to optimize the treatment of the method of Bairey et al.

There would have been a reasonable expectation of success given that each of the agents was known to be utilized for the same purpose as chemotherapeutic agents. Furthermore, there would have been a reasonable expectation of success at optimizing the dosage ranges, sequence of administration of the agents, as well as administration of the immunosuppressant during allogeneic stem cell transplantation given the

teachings of the prior art. There would have been a reasonable expectation of success given each of the elements are basic alterations to the timing of the methods of Bairey et al. and Sayer et al. that are within the realm of routine optimization. Importantly, Bairey et al. and Sayer et al. establish that it was known in the art to combine the treatment of immunosuppressants and defibrotide, wherein defibrotide treatment resulted in a dramatic response without further toxicity.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to arguments that are pertinent to the instant rejection

Regarding Sayer et al., applicant argues the intended use of the method because Sayer et al. teaches treating veno-occlusive disease rather than protecting epithelial and/or endothelial cells. It is noted that the instant method is directed to a method of treating a patient, which is an element that is taught by Sayer et al. The method of Sayer et al. comprises administering defibrotide, which necessarily meets the formula of claim 3 from which claim 7 depends and further defines the oligodeoxyribonucleotide as being defibrotide. Sayer et al. teaches administering an immunosuppressant in combination with defibrotide and is not required to teach the instantly recited outcome. Since Sayer et al. teaches a method of administering an immunosuppressant in combination with defibrotide to treat a patient, there need only be motivation to utilize an immunosuppressant which comprises a nucleoside, which is addressed in the rejection

under 35 USC 103(a) above. The method would necessarily then have the instantly recited outcome if each of the method steps are obvious.

Applicant asserts that the parameters of claim 3 yield unexpected results because defibrotide demonstrated protection of HMEC cells from F-ara-induced apoptosis. It is noted that these are not elements required by claim 3 and do not demonstrate any unexpected properties of the method of claim 3 in view of the teachings of Sayer et al. that defibrotide enhances tPA and thrombomodulin in endothelial cell cultures and Bairey et al. that defibrotide increases fibrinolysis and may possess antithrombotic, anti-ischemic, and anti-inflammatory properties without significant anticoagulant effects. Bairey et al. teaches that defibrotide can avidly bind to vascular endothelium and increase the levels of endogenous prostaglandins and stimulate expression of thrombomodulin and that for these reasons defibrotide was selected to treat a condition, VOD, which was previously fatal (se page 283, column 2). Therefore, one would expect for such treatment to result in the instant outcome.

Since Sayer et al. and Bairey et al. each teach a method of treating a patient via administering an immunosuppressant in combination with defibrotide treatment to treat VOD, which is a life threatening complication following allogeneic stem cell transplantation, there is certainly motivation in the art to utilize immunosuppressants in combination with defibrotide during or after allogeneic stem cell transplantation. Based upon the successful reporting of Sayer et al., one would have been motivated to utilize other immunosuppressants as well.

The patient of Sayer et al. had high grade B-cell lymphoma and the patient of Bairey et al. had acute monoblastic leukemia. Each teach combining defibrotide with immunosuppressant treatment and therefore one would have been motivated to utilize 5-fluorouracil as the immunosuppressant, as it was known that 5-fluorouracil was a commonly used chemotherapeutic agent.

Therefore, each of the instant method steps are obvious in combination to treat a patient and would necessarily have the instantly recited outcome.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMY BOWMAN
Examiner
Art Unit 1635

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Examiner, Art Unit 1635